

ERYTHROMYCIN - erythromycin solution

Perrigo New York, Inc.

Rx only

DESCRIPTION

Erythromycin is an antibiotic produced from a strain of *Streptomyces erythraeus*. It is basic and readily forms salts with acids.

Contains: erythromycin, USP2% (20 mg/mL)

with SD Alcohol 40A (66%), propylene glycol and citric acid to adjust pH.

CLINICAL PHARMACOLOGY

Although the mechanism by which Erythromycin Topical Solution acts in reducing inflammatory lesions of acne vulgaris is unknown, it is presumably due to its antibiotic action.

INDICATIONS AND USAGE

Erythromycin Topical Solution is indicated for the topical control of acne vulgaris.

CONTRAINDICATIONS

Erythromycin Topical Solution is contraindicated in persons who have shown hypersensitivity to erythromycin or any of the other listed ingredients.

WARNINGS

The safe use of Erythromycin Topical Solution during pregnancy or lactation has not been established.

PRECAUTIONS

General

The use of antibiotic agents may be associated with the overgrowth of antibiotic-resistant organisms. If this occurs, administration of this drug should be discontinued and appropriate measures taken.

Information for patients

Erythromycin Topical Solution is for external use only and should be kept away from the eyes, nose, mouth and other mucous membranes. Concomitant topical acne therapy should be used with caution because a cumulative irritant effect may occur, especially the use of peeling, desquamating or abrasive agents.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies to evaluate carcinogenic potential, mutagenicity or the effect on fertility of erythromycin have not been performed.

Pregnancy

Pregnancy Category C. Animal reproduction studies have not been conducted with erythromycin. It is also not known whether erythromycin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Erythromycin should be given to a pregnant woman only if clearly needed.

Nursing Mothers

Erythromycin is excreted in breast milk. Caution should be exercised when erythromycin is administered to a nursing woman.

ADVERSE REACTIONS

Adverse conditions reported with the use of erythromycin topical solutions include dryness, tenderness, pruritus, desquamation, erythema, oiliness, and burning sensation. Irritation of the eyes has also been reported. A case of generalized urticarial reaction, possibly related to the drug, which required the use of systemic steroid therapy, has been reported.

DOSAGE AND ADMINISTRATION

Erythromycin Topical Solution should be applied to the affected area(s) each morning and evening after the skin is thoroughly washed with warm water and soap and patted dry. Use enough solution to thoroughly wet the affected area(s). The hands should be washed after application. Acne lesions on the face, neck, shoulder, chest, and back may be treated in this manner. When using the Dab-O-Matic applicator to apply Erythromycin Topical Solution, it should be moistened first by holding the bottle upside down and pressing once on the applicator surface with a clean finger. Then Erythromycin Topical Solution can be applied with the applicator to the affected area(s) using a dabbing motion. The bottle should be closed tightly after each use.

HOW SUPPLIED

Erythromycin Topical Solution USP, 2% is supplied in a 60 mL plastic bottle with optional Dab-O-Matic applicator.

Note: FLAMMABLE. Keep away from heat and flame. Store in tight, light resistant container at controlled room temperature 15° to 30°C (59° to 86°F).

MFG. BY: CLAY-PARK LABS, INC. BRONX, NEW YORK 10457.

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